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April 18, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the Great Lakes Chemical Corporation's HPV Test Plans for Isopropylated Triphenyl Phosphate and Tricresyl Phosphate

Dear Administrator Whitman:

The following comments on the Great Lakes Chemical Corporation's (GLCC's) test plans for the individual chemicals isopropylated triphenyl phosphate and tricresyl phosphate are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The GLCC's test plans for isopropylated triphenyl phosphate and tricresyl phosphate suffer from the same problems as Akzo Nobel's test plans for trixylenyl phosphate and butylated triphenyl phosphate. The GLCC's test plans constitute two more examples of poorly researched, thoughtless test plans that will provide little understanding of the potential hazards of these or related compounds.

The test plan for isopropylated triphenyl phosphate calls for genetic, reproductive, and developmental toxicity tests, and the test plan for tricresyl phosphate proposes a developmental toxicity test. These tests could kill as many as 2,840 animals.

As with the Akzo Nobel plans, the GLCC's test plans violate the following terms of the October 1999 Agreement among the EPA, industry, and health, animal protection, and environmental organizations, which delineated certain principles for eliminating repetitive or irrelevant testing on animals:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach.
2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.
3. Participants shall maximize the use of scientifically appropriate categories of related chemicals and structure activity relationships.

5. Participants are encouraged to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use.

Our main comments on the test plan are as follows:

- The Great Lakes Chemical Corporation should include isopropylated triphenyl phosphate into a broader group of structurally similar compounds.
- The test plan is incomplete and lacks transparency, a fundamental component of the HPV program.

Category Expansion

Isopropylated triphenyl phosphate could easily be grouped into a larger category of phenyl-phosphate compounds. ATSDR has already generally grouped many of these compounds together in a phosphate-based hydraulic fluid category in its review of the toxicity of hydraulic fluids.¹ A table of other phenyl phosphorus HPV compounds is presented in our comments on the Phosphite Producers HPV Consortium's test plan for tris(nonylphenyl)phosphite, which can be viewed at <http://www.epa.gov/chemrtk/phsphite/trispcrmct.pdf>.

Lack of Transparency

The test plans and robust summaries do not provide even the most basic information about these chemicals, such as their molecular weight, structure, use, behavior, or characteristics. Although the test plans call for testing for genetic, reproductive, and developmental endpoints, the GLCC fails to mention the planned test protocol or OECD guideline, fails to describe whether the reproductive and developmental toxicity tests will be combined or conducted separately, fails to discuss the results of the repeat dose study that did examine reproductive endpoints, fails to explain whether the genetic toxicity tests will be conducted *in vitro* or *in vivo*, and fails to present any references to the abundant existing data for these compounds.

In addition, the plans do not outline any of the human exposure or health data available on these chemicals or similar chemicals. Significant data exist on human toxicity and epidemiology of phosphate-based hydraulic fluids identifying them as potential neurotoxins.² In addition, they are suspected endocrine disrupting chemicals.¹ Concern over the adverse health effects associated with these chemicals has prompted ongoing research efforts into the behavior and metabolism of this group of compounds. Conducting screening-level tests on these well-studied chemicals is therefore highly inappropriate.

The GLCC simply submitted a downloaded list of the studies available in the IUCLID format, without providing a context for the existing data. The GLCC neglected to discuss the overall context and behavior of this larger group of well-studied chemicals, therefore completely ignoring one of the primary stated objectives of the HPV program, i.e., to provide available information on the potential health and environmental hazards of these industrial chemicals.

In conclusion, we find that the GLCC's test plans are incomplete and lack any meaningful presentation of data required to pass the most minimal standard of thoughtful toxicology. As we commented previously, many of these phosphate compounds should be combined into a single category of aryl phosphates to maximize the availability of abundant information of structurally similar chemicals.

The test plans submitted by the GLCC are entirely insufficient from the perspectives of fundamental

scientific documentation, toxicological rigor, and compliance with the most rudimentary guidance for the HPV program, especially in regard to animal welfare issues. In order to demonstrate good faith in the HPV program and adherence to the October 1999 Agreement, the GLCC must provide a more thoughtful analysis of these chemicals and their fundamental uses and properties.

Once again, we maintain that it is critical that the EPA play a leadership role in encouraging the development of chemical categories to maximize available information and avoid unnecessary, expensive, and poorly conceived testing. It is imperative that the EPA take proactive steps to address the submission of such inadequate plans to the HPV program. The EPA should reject these test plans in their current forms and ask the GLCC to submit a more thoughtful presentation of the available information on these chemicals.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or via e-mail at ncardello@pcrm.org.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist

References

1. ATSDR. *Toxicological Profile of Hydraulic Fluids*. 1997. Found at <http://www.atsdr.cdc.gov/toxprofiles/tp99-c3.pdf>.
2. Inchem. *International Programme On Chemical Safety*. Environmental Health Criteria 110. Tricresyl Phosphate. 1990. Found at <http://www.inchem.org/documents/ehc/ehc/ehc110.htm>.